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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/624,380   | 07/22/2003  | Robert Mulroy        | 06727/012001        | 1018             |
| 21559  | 7590        | 03/28/2006           | EXAMINER            |                  |
| CLARK & ELBING LLP<br>101 FEDERAL STREET<br>BOSTON, MA 02110 |             |                      | CROUCH, DEBORAH     |                  |
|  |             | ART UNIT             |                     | PAPER NUMBER     |
|  |             |                      |                     | 1632             |

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/624,380             | MULROY ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Deborah Crouch, Ph.D.  | 1632                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 1-76 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. ____ .   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____ .                                   |

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Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, 42-48 and 76, drawn to a nucleic acid encoding a non-glycosylated human AFP (ng.huAFP), a method of producing nghuAFP in cell culture.

Group II, claim(s) 16-19, drawn to an nghuAFP.

Group III, claim(s) 20-27, 34-41, 49 and 50-53, drawn to a transgenic mammal expressing nghuAFP in milk, milk and method of producing nghuAFP in milk.

Group IV, claim(s) 20-25, 28, 29, 34, 35, 50 and 54-56, drawn to a transgenic mammal expressing nghuAFP in urine, urine and method of producing ng.huAFP in urine.

Group V, claim(s) 20-25, 30, 31, 36, 37, 50 and 57-59, drawn to a transgenic mammal expressing nghuAFP in blood, blood and method of producing ng.huAFP in blood.

Group VI, claim(s) 20-25, 32, 33, 40, 41, 50 and 60-62, drawn to a transgenic mammal expressing nghuAFP in lymph, lymph and method of producing ng.huAFP in lymph.

Group VII, claim(s) 63-67, drawn to methods of treatment comprising administering a therapeutically effect amount of ng.HuAFP and a therapeutic composition comprising ng.HuAFP.

Group VIII, claim(s) 68 and 69 drawn to method to make a medicament comprising ng.HuAFP to treat an immunological disorder.

Group VIII, claim(s) 70 and 71 drawn to method to make a medicament comprising ng.HuAFP to treat an autoimmune disorder.

Group VIII, claim(s) 72 and 73 drawn to method to make a medicament comprising ng.HuAFP to cause immunosuppression.

Group VIII, claim(s) 74, drawn to method to make a medicament comprising ng.HuAFP to treat the side effects of chemotherapy.

Group VIII, claim(s) 75, drawn to method to make a medicament comprising ng.HuAFP for enhancing cell proliferation.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding

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special technical features for the following reasons: Semeniuk et al teaches that human AFP lacking glycosylation can be produced by expressing cDNA sequences in bacterial or yeast cells (page 263, parag. 3, lines 1-4). This form of AFP retained its immunosuppression activity (page 255, lines 16-19). Thus, the concept of AFT lacking glycosylation was known in the art at the time of filing, meaning the claimed invention lacks a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch,  
Primary Examiner  
Art Unit 1632

March 17, 2006